

REMARKS

This Amendment is submitted in response to the non-final Office Action mailed on July 7, 2008. No fee is due in connection with this Response. The Director is authorized to charge any fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-706 on the account statement.

Claims 1-12 and 14-15 are pending in this application. Claims 6-8, 12 and 14-15 were previously withdrawn and Claim 13 was previously canceled without prejudice or disclaimer. In the Office Action, Claims 1-5 and 9-11 are rejected under 35 U.S.C. §112. Claims 1-5 and 9-11 are further rejected under 35 U.S.C. §103. In response, Claims 1 and 9-11 have been amended. These amendments do not add new matter. In view of the amendments and/or for at least the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claims 1-5 and 9-11 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. The Patent Office asserts that the limitation “substantially free” in Claims 1 and 9-11 is not defined by the claim such that one of ordinary skill in the art would be reasonably apprised of its meaning. See, Office Action, page 3, lines 4-9. In response, Applicants have amended Claims 1 and 9-11 to recite, in part, a natural lycopene concentrate wherein the concentrate is isolated from fibers and other insoluble compounds by solid-liquid separation. These amendments do not add new matter. These amendments are supported in the Specification, for example, at page 1, paragraphs 20-21; page 2, paragraphs 27, 36 and 39-40. One of ordinary skill in the art would understand that fibers and other insoluble compounds are removed from the concentrate of the present claims by a solid-liquid separation. As such, the concentrate of the present claims is isolated or free from fibers and other insoluble compounds to the extent provided by a solid-liquid separation. Thus, Applicants respectfully submit that Claims 1-5 and 9-11 are not indefinite.

The Patent Office further asserts that Claim 9 is indefinite due to the use of the abbreviated term “UV” rather than the full name corresponding to “UV.” See, Office Action, page 3, lines 10-11. In response, Applicants have amended Claim 9 to replace the term “UV” with “ultraviolet light.” This amendment does not add new matter. This amendment is supported in the Specification, for example, at page 2, paragraphs 43 and 49. Therefore, Applicants respectfully submit that currently amended Claim 9 is not indefinite.

Accordingly, Applicants respectfully request that the rejection of Claims 1-5 and 9-11 under 35 U.S.C. §112, second paragraph, be withdrawn.

In the Office Action, Claims 1-5 and 9-11 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Application No. 2002/0107292 A1 to Bortlik et al. ("*Bortlik*") in view of U.S. Patent No. 5,837,311 to Zelkha et al. ("*Zelkha*"). In response, Applicants have amended Claims 1 and 9-11. In view of the amendments and/or for at least the reasons set forth below, Applicants respectfully submit that the cited references fail to disclose or suggest each and every element of independent Claims 1 and 9-11 and Claims 2-5 that depend therefrom.

Independent Claims 1 and 9-11 recite, in part, a natural lycopene concentrate that is water-soluble at room temperature comprising at least 1 mg of lycopene per g of the said concentrate, not more than 30% of proteins, not more than 30% of polysaccharides, not more than 10% of organic acids, and at least 30% of lipid compounds, wherein the concentrate is isolated from fibers and other insoluble compounds by solid-liquid separation, and wherein the concentrate is extracted from a lycopene-containing material without the use of a solvent. Conventional lycopene-containing preparations are obtained by extraction using a solvent. See, Specification, paragraphs 3-6. Traces of solvent are thus likely to be found in the finished lycopene product. See, Specification, paragraph 3, lines 4-7. However, the solvent may modify the native characteristics of the lycopene product. See, Specification, paragraph paragraphs 3-7. Therefore, the present claims recite a natural lycopene concentrate that is extracted from a lycopene-containing material without the use of a solvent in order to preserve the natural characteristics of the lycopene and thereby provide a concentrate with a high bioactivity. See, Specification, paragraph 20, lines 4-9. The concentrate is prepared by alkalinizing a lycopene-containing material under heat and isolating the lycopene from the fibers and other insoluble compounds by solid-liquid separation. See, Specification, paragraphs 25-27. The lycopene-containing solution is then acid-precipitated from the filtrate and separated from carbohydrates and other soluble compounds by solid-liquid separation. See, Specification, paragraphs 37-39. A solvent is not necessary because the process for obtaining the lycopene concentrate is based on the pH-dependent "solubility" of lycopene from lycopene-containing materials such as tomato paste. In contrast, the cited references fail to disclose every element of the present claims.

For example, the cited references fail to disclose or suggest a natural lycopene concentrate, wherein the concentrate is extracted from a lycopene-containing material without

the use of a solvent as required, in part, by the present claims. *Bortlik* is entirely directed to a lipophilic bioactive extract obtained by the use of a solvent. See, *Bortlik*, paragraph 9, lines 4-14. *Bortlik* specifically discloses that its lycopene extract is “obtained by conventional methods, with the preferred totmato [sic] extract being a lipidic extract obtained by use of a solvent such as ethyl acetate.” See, *Bortlik*, paragraph 14, lines 8-10. In fact, all of the embodiments and examples disclosed in *Bortlik* involve the use of a solvent to obtain the lipophilic bioactive compound. See, *Bortlik*, paragraphs 32-37, 40 and 49-51. Therefore, *Bortlik* fails to disclose or suggest a natural lycopene concentrate, wherein the concentrate is extracted from a lycopene-containing material without the use of a solvent.

Zelkha is also directed to the use of a solvent to obtain a lycopene oleoresin. See, *Zelkha*, Abstract, lines 6-10. For example, the process of *Zelkha* comprises the step of subjecting a tomato pulp to solvent extraction in order to obtain an oleoresin containing lycopene. See, *Zelkha*, column 2, lines 28-40. Although *Zelkha* discloses that the tomato pulp may be extracted using solvents or finely ground into a new product, the finely ground product contains most of the tomato insoluble solids and is not a lycopene concentrate that is isolated from fibers and other insoluble compounds as required by the present claims. See, *Zelkha*, column 3, lines 49-55. As the Patent Office admits, the lycopene concentrate of *Zelkha* is the lycopene oleoresin that is extracted from the tomato. See, Office Action, page 4, lines 23-24; page 5, lines 1-8. The lycopene oleoresin is “obtained by an appropriate choice of solvents.” See, *Zelkha*, column 4, lines 57-65; column 5, lines 14-16. As such, the cited references fail to disclose or suggest a natural lycopene concentrate, wherein the concentrate is extracted from a lycopene-containing material without the use of a solvent as recited, in part, by the present claims.

Moreover, the cited references fail to disclose or suggest a natural lycopene concentrate that is isolated from fibers and other insoluble compounds by solid-liquid separation as required, in part, by the present claims. The Patent Office admits that *Bortlik* fails to disclose or suggest that the concentrate is free or isolated from fibers and other insoluble compounds and instead relies on *Zelkha* for the claimed element. See, Office Action, page 4, lines 20-24; page 5, lines 1-8 and 13-17. However, the portions of *Zelkha* relied on by the Patent Office merely disclose separating fibers and insoluble solids from a lycopene oleoresin that is obtained by extraction with a solvent. See, *Zelkha*, column 7, lines 49-61. Because the solvent may modify the native characteristics of the lycopene in the oleoresin, the oleoresin is not a natural concentrate. See,

Specification, paragraph 20.

The only natural lycopene-containing product disclosed in *Zelkha* is the finely ground pulp product. See, *Zelkha*, column 3, lines 49-51. However, “the finely ground pulp is a new product, which is characterized in that it contains most of the tomato insoluble solids.” See, *Zelkha*, column 3, lines 51-53. As such, the finely ground pulp product of *Zelkha* is not isolated from fibers and other insoluble compounds. Thus, the cited references fail to disclose or suggest a natural lycopene concentrate that is isolated from fibers and other insoluble compounds by solid-liquid separation in accordance with the present claims.

Accordingly, Applicants respectfully request that the rejection of Claims 1-5 and 9-11 under 35 U.S.C. §103(a) to *Bortlik* in view of *Zelkha* be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims that could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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